Stratton VA Medical Center
IRB Standard Operating Procedure: IRB Record Keeping

POLICY

It is Stratton VA Medical Center's policy to comply with all applicable federal, state and local regulations, and ICH guidelines in the conduct of human subject research studies. Written procedures are required to detail maintenance of adequate documentation of IRB activities.

REFERENCE DOCUMENTS

45 CFR

21 CFR 50, 56

38 CFR 16

VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research

PROCEDURE

IRB records – in accordance with VHA Handbook 1200.5, "Requirements for the Protection of Human Subjects in Research," the IRB records relating to research will be retained indefinitely. These records will be stored in designated and secured areas within the Stratton VA Medical Center. IRB records include:

- Protocols
- IRB applications
- Scientific evaluations
- DHHS-approved sample consent document and protocol, when they exist.
- For initial and continuing review of research by the expedited procedure:
    - The specific permissible category
    - Description of action taken by the reviewer
    - Any findings required under the regulations
- For exemption determinations, the specific category of exemption
- Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
    - Waiver or alteration of the consent process
    - Research involving pregnant women
- For each protocol's initial and continuing review, the frequency for the next continuing review
- Correspondence between the IRB and the Research and Development Committee
- Unexpected adverse events submitted to the IRB
- Protocol violations submitted to the IRB

- A resume for each IRB member
- All initial submission documents
- All approval letters
- All reviewed correspondence with a Principal Investigator or designated contact person
- Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation
- All Continuing Review submissions and any attachments received are filed in the protocol files.
- If the research is disapproved for continuation, a Notification of Disapproval letter is filed in the protocol file.
- IRB Standard Operating Procedures
- IRB Membership rosters
- IRB training records
- IRB research project files
- IRB meeting minutes
- Reports of injuries to participants
- Other pertinent documentation
- Disapproved Protocols

Files of new research disapproved by the IRB are held in the Research Office. A Notification of Disapproval letter is placed in the protocol file.

If a Principal Investigator resubmits the protocol, the modified protocol submission is filed in the original protocol file otherwise the file will be retained indefinitely.

Closed Protocols

When a Notification of Closure is issued, the closed protocol file is forwarded to the R&D Committee for final closure. The file is then removed from the Research Office filing system and archived outside the Research Office in a secure location within the institution.

Currently, all Research related VA information will be kept indefinitely. The VA Research information will always be kept at least as long as required by any protocol specific overseeing agency/organization's minimum retention requirement.

When a protocol is cancelled without participant enrollment the VA study files shall be retained indefinitely.

Minutes of IRB meetings are kept in the Research Office; they will include pertinent discussions and decisions on the research studies and activities, such as:

1. Approval period for initial and continuing review

2. Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.

3. The rationale for significant risk/non-significant risk device determinations.

4. The approval of research contingent on specific minor conditions by the chair or designee; to be documented in the minutes of the first IRB meeting that took place after the date of approval.

5. The determination of the level of risk

6. Actions taken by the IRB

7. Separate deliberations for each action

8. The names of IRB members who left the meeting because of a COI, along with the fact that a conflicting interest is the reason for the absence

When determinations were required by the regulations, protocol-specific findings justifying those determinations for:

1. Waiver or alteration of the consent process

2. Waiver of consent documentation

3. Research involving vulnerable participants

Evaluation of whether the research involves participants vulnerable to coercion, undue influence or impaired decision-making capacity and whether additional safeguards to protect the rights and welfare of the participants need to be included.

Copies of all approved IRB minutes are forwarded to the R&D Committee for review and approval. All IRB records will be accessible to R&D members at any time.

The IRB minutes that are approved by the IRB members at a subsequent IRB meeting can not be altered by anyone, including a higher authority.

A list of current IRB members is maintained on the research website by the Research Office and is updated as changes occur and changes are reported to the Office of Human Research Protections (OHRP).

IRB staff maintains a file of the curricula vitae of current IRB members that is updated annually.

Requests for access to IRB records by VA representatives or other federal agencies must be made through the Research Administration Office at reasonable times and in a reasonable manner. Copies of IRB records will be granted only with proper approval.

Records that pertain to clinical investigations regulated by the Food & Drug Administration (FDA) will be accessible for inspection and copying by authorized representatives of the FDA at reasonable times and in a reasonable manner.

The electronic database system (MIRB) tracks all events related to the research, such as initial review, continuation review, AE's, as well as the documents submitted that are related to the events.

IRB records and Investigator records are the property and the responsibility of the Stratton VA Medical Center.

Standard Operating Procedures specific to Department of Defense (DOD) Research

May require submitting records to Department of Defense for archiving.